Exhibit B

EXHIBIT B
COMPARISON OF CITED PORTIONS OF MICHELSON DISCLOSURE TO DISCLOSURE OF '634 PROVISIONAL APPLICATION

July 14, 2006 Office Action Assertions by Examiner	**Disclosure Referred to by Examiner in Michelson *et al.*, U.S. Patent Pub. No. 2002/0002474 A1**	**Disclosure in Michelson *et al.*, U.S. Provisional Appl. No. 60/178,634**	**Claim Rejections In Which Examiner Specifically Relies on Cited Portion of Michelson *et al.*, U.S. Patent Pub. No. 2002/0002474 A1**
"Michelson et al. teaches the claimed personally-identifying information includes a registration number of the individual. This limitation is met by the registration information including user id and password (see: paragraph 10)"	[0010] The present invention is also directed to a method for recruiting a person to participate as a subject in a clinical study. One or more web pages are presented that allow the person or a caregiver associated with the person to register with a database by submitting registration and permission information to the database. The registration information includes, for example, a user id, a password, preferred contact information (i.e., an electronic mail address or telephone number), zip code, first name or preferred name, gender, date of birth, whether the person or caregiver is interested in clinical study information, and whether the person or caregiver is interested in new medical therapies. The permission information includes whether the person or caregiver is interested in receiving notice of clinical studies. The person or caregiver is automatically	There is no explicit disclosure in the provisional application of user id and password based registration for potential subjects of clinical trials. The provisional application states, "The web site 320 has three tiers of access. … Tier 1 is available to the general public … Tier 2 is available to authorized users, such as those confirmed to be in the pharmaceutical industry. … Tier 3 permits access to the databases, and are generally for the sponsors of clinical trials." (See, page 8). The provisional application further states, "There are also multiple Internet health care portals so that an Internet	213, 236, 237, 248

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	registered with the database upon receipt of the registration and permission information. Next, an automatic determination is made, in accordance with the permission information and the registration information, as to whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the person. The person or caregiver is provided notice of the given clinical study only if the system automatically determines that such notice should be sent. A questionnaire associated with the given clinical study may also be provided automatically to the person or caregiver, if the person or caregiver indicates interest in the clinical study in response to the notice. Answers submitted by the person or caregiver to the questionnaire are then stored in the database. The stored questionnaire answers, along with other information stored in the database, may be accessed to determine whether the person should be pre-screened for participation as a subject in a clinical study different from the given clinical study.	Patient recruitment program that is study and site-specific can be initiated." (See, page 8). The provisional application also states, "The system includes software that supports account sign-up, management, demographics capture, and personalization of target audiences." (See, page 9). Although the provisional application contemplates (1) providing different levels of access to the general public, pharmaceutical industry users, and sponsors and (2) supporting account sign-up, it does not explicitly disclose a user id and password based registration process for potential subjects of clinical trials. As suggested by Michelson, registration means other than a user id and password login may have been intended (for example, access by e-mail address only).	
"Michelson et al. teaches … at	[0095] Upon clicking on contact area 604,	There is no explicit disclosure	207, 226, 242

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area 607 [FIG. 6C], where a registered user may select up to three therapeutic area (clinical research areas) in which the user is interested (see: paragraph 95)"	the user will be taken to general study interest web page 605 shown in FIG. 6C. On general study interest web page 605, the registered user may indicate in interest area 606 whether the registered user is interested for himself/herself or for someone else. In one embodiment, the registered user may select in selection area 607 up to three therapeutic areas in which the registered user is interested. In contact area 608, the registered user indicates the manner in which the registered user would like to be contacted, e.g., by e-mail, telephone or regular mail. The registered user also indicates name and contact information in contact information area 609. The registered user submits the form by clicking on submit button 610, or may cancel the process by clicking on cancel button 611.	in the provisional application of a system that allows a user to select up to three therapeutic areas of interest to search for clinical studies. There is no FIG. 6C or any similar figure disclosed. The provisional application states, "the inventive system software enables patients to identify clinical trials for which they may enroll." (See page 10). Although the provisional application contemplates that patients may identify and enroll in individual clinical trials of interest on a case-by-case basis, the provisional application does not disclose a system that enables registered users to identify and select up to three therapeutic areas of interest via a general interest web page.	
"Michelson et al. teaches that in order to become a user	[0097] In an alternative embodiment, in order to become a user registered with the	The alternative embodiment of paragraph [0097] is not	204, 206, 210, 211, 212, 215, 217, 218, 219, 220,

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registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number and additional information such as date of birth (see: paragraph 97)"	subject database, the user will be required to provide the information required as shown in the web page depicted in FIG. 6D: a user id; password; password reminder; and whether the user is seeking information for himself or herself or for someone else. In a second step, with reference to FIG. 6E, the user will be required to provide additional information such as first name, date of birth, gender, electronic mail address, zip code and an indication of one or more medical conditions in which the user is interested. Additional information, though not required for registration, may be provided such as medical conditions experienced by the user, salutation, last name, ethnic background, telephone number, country of residence, as shown in FIG. 6E. In a third step 3, the user inputs information on a web page such as that shown in FIG. 6F, including a request to receive various types of information (such as, e.g., clinical study opportunities or news and new medical therapies) about the user's medical conditions identified in FIG. 6E. The user may request that he or she not be sent any information. In area 650, the user is asked to agree to certain terms and conditions	disclosed. In particular, there is no explicit disclosure in the provisional application of an embodiment of the invention requiring a registered user to provide the information depicted in FIGs. 6D - 6M of Michelson. There are no FIGs. 6D, 6E or any similar figures disclosed. The provisional application states, "The system also includes a patient database 310. The patient database is constructed as to protect the patients' privacy, and includes information about individual patients, such as relevant clinical data, zip code of residence, and e-mail addresses. This database is created through solicitations in advertisements on other Internet sites, through collection of billing and other data from the physician practice management systems of the physician investigators who	221, 222, 223, 226, 228, 233, 234, 235, 237, 238, 239, 245, 246, 247, 249, 250, 251, 252, 253

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	governing the user's use of the inventive system. Upon completing the required information and accepting the terms and conditions, the user will become a registered user of the inventive system, as shown in the web page depicted in FIG. 6G. At this point, the user may choose to answer additional, optional questions or to return to the previous activity. If the user chooses to answer additional questions, the user may be taken to a web pages such as those depicted in FIGS. 6H through 6J and provide information such as the type of prescriptions or over-the-counter medications taken by the user for a given medical condition; the health habits of the user; and the clinical study experience of the user. In FIG. 6K, the user can see if the user has answered completely questions about each medical condition previously listed by the user. In FIG. 6L, the user can provide feedback. In FIG. 6M, the service provider may provide a thank you to indicate that the message was sent successfully.	have private practices, and through managed care organizations, employers, hospital systems, prescription benefit manager, disease management companies, disease advocacy groups, and physician practice management companies. Further information may be collected from pathology labs to provide more detail about the disease status of oncology patients." (See, page 7). The provisional application further states, "[there] also are multiple Internet health care portals so that an Internet patient recruitment program that is study and site-specific can be initiated." (See, page 8). The provisional application also states, "The web site 320 has three tiers of access. … Tier 1 is available to the general public … Tier 2 is available to authorized users, such as those	

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		confirmed to be in the pharmaceutical industry. … Tier 3 permits access to the databases, and are generally for the sponsors of clinical trials." (See, page 8). The provisional application in addition states, "[the] software includes proprietary database matching that enables a comparison of the participant profile to the trials protocol criteria. For example, templates are established for certain protocols and performing database matching to compare this information against the participant entered data." (See, page 9). The provisional application does not explicitly disclose a web based system whereby potential subjects are required to disclose the information depicted in FIGs. 6D and 6E in order to become registered with a subject database. The	

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		provisional application merely suggests that the patient database may be populated with information provided by patients attempting to enroll in a clinical trial, and with information gathered from a number of other secondary sources other than from the patients themselves. (See, page 7). While the provisional application indicates that a comparison of a "participant profile to the trials protocol criteria" can be made against "participant entered data," it does not explicitly define a specific definition for "participant," and more particularly, does not disclose or suggest that a participant is a patient (subject) who registers with the subject database to directly disclose the information depicted in FIGs. 6D, 6E. Rather, based on disclosure at pages 7 and 8, the provisional	

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		application more reasonably suggests that the information depicted in FIGs. 6D, 6E, if registered at all, is registered at the web site by other secondary means.	
"Michelson et al. teaches in area 650 [Figure 6F], the user is asked to agree to terms and conditions governing the system and upon completion of the required information and accepting the terms and conditions, the user become a registered users and at this point the user may choose to answer additional questions such as health survey questions (see: paragraph 97)"	[0097] In an alternative embodiment, in order to become a user registered with the subject database, the user will be required to provide the information required as shown in the web page depicted in FIG. 6D: a user id; password; password reminder; and whether the user is seeking information for himself or herself or for someone else. In a second step, with reference to FIG. 6E, the user will be required to provide additional information such as first name, date of birth, gender, electronic mail address, zip code and an indication of one or more medical conditions in which the user is interested. Additional information, though not required for registration, may be provided such as medical conditions experienced by the user, salutation, last name, ethnic background, telephone number, country of residence, as shown in FIG. 6E. In a third step 3, the user inputs information on a web page such as that shown in FIG. 6F,	The alternative embodiment of paragraph [0097] is not disclosed. In particular, there is no explicit disclosure in the provisional application of an embodiment of the invention providing that a user agree to terms and conditions governing the system, and upon providing required information and accepting the terms and conditions, becoming registered with the system. There is no Figure 6F or any similar figure disclosed. The provisional application states, "The system also includes a patient database 310. The patient database is constructed as to protect the patients' privacy, and includes	204, 210, 215, 217, 226, 228, 229, 239, 245

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	including a request to receive various types of information (such as, e.g., clinical study opportunities or news and new medical therapies) about the user's medical conditions identified in FIG. 6E. The user may request that he or she not be sent any information. In area 650, the user is asked to agree to certain terms and conditions governing the user's use of the inventive system. Upon completing the required information and accepting the terms and conditions, the user will become a registered user of the inventive system, as shown in the web page depicted in FIG. 6G. At this point, the user may choose to answer additional, optional questions or to return to the previous activity. If the user chooses to answer additional questions, the user may be taken to a web pages such as those depicted in FIGS. 6H through 6J and provide information such as the type of prescriptions or over-the-counter medications taken by the user for a given medical condition; the health habits of the user; and the clinical study experience of the user. In FIG. 6K, the user can see if the user has answered completely questions about each medical condition previously listed by the user. In FIG. 6L, the user can	information about individual patients, such as relevant clinical data, zip code of residence, and e-mail addresses. This database is created through solicitations in advertisements on other Internet sites, through collection of billing and other data from the physician practice management systems of the physician investigators who have private practices, and through managed care organizations, employers, hospital systems, prescription benefit manager, disease management companies, disease advocacy groups, and physician practice management companies. Further information may be collected from pathology labs to provide more detail about the disease status of oncology patients." (See, page 7). The provisional application further states, "[there] also are multiple Internet health care	

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	provide feedback. In FIG. 6M, the service provider may provide a thank you to indicate that the message was sent successfully.	portals so that an Internet patient recruitment program that is study and site-specific can be initiated." (See, page 8). The provisional application in addition states, "[the] software includes proprietary database matching that enables a comparison of the participant profile to the trials protocol criteria. For example, templates are established for certain protocols and performing database matching to compare this information against the participant entered data." (See, page 9). The provisional application does not explicitly disclose a web interface that requires a user to agree to terms and conditions governing the system in order to become registered with a subject database.	
"Michelson et al. teaches that a user will be required to provide user id and password in order	[0097] In an alternative embodiment, in order to become a user registered with the subject database, the user will be required	The alternative embodiment of paragraph [0097] is not disclosed. In particular, there is	210, 223, 238, 245, 249

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to register with the subject database (see: paragraph 97)."	to provide the information required as shown in the web page depicted in FIG. 6D: a user id; password; password reminder; and whether the user is seeking information for himself or herself or for someone else. In a second step, with reference to FIG. 6E, the user will be required to provide additional information such as first name, date of birth, gender, electronic mail address, zip code and an indication of one or more medical conditions in which the user is interested. Additional information, though not required for registration, may be provided such as medical conditions experienced by the user, salutation, last name, ethnic background, telephone number, country of residence, as shown in FIG. 6E. In a third step 3, the user inputs information on a web page such as that shown in FIG. 6F, including a request to receive various types of information (such as, e.g., clinical study opportunities or news and new medical therapies) about the user's medical conditions identified in FIG. 6E. The user may request that he or she not be sent any information. In area 650, the user is asked to agree to certain terms and conditions governing the user's use of the inventive	no explicit disclosure in the provisional application of user id and password based registration for potential subjects of clinical trials. The provisional application states, "The web site 320 has three tiers of access. ... Tier 1 is available to the general public ... Tier 2 is available to authorized users, such as those confirmed to be in the pharmaceutical industry. ... Tier 3 permits access to the databases, and are generally for the sponsors of clinical trials." (See, page 8). The provisional application further states, "There are also multiple Internet health care portals so that an Internet Patient recruitment program that is study and site-specific can be initiated." (See, page 8). The provisional application also states, "The system includes	

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	system. Upon completing the required information and accepting the terms and conditions, the user will become a registered user of the inventive system, as shown in the web page depicted in FIG. 6G. At this point, the user may choose to answer additional, optional questions or to return to the previous activity. If the user chooses to answer additional questions, the user may be taken to a web pages such as those depicted in FIGS. 6H through 6J and provide information such as the type of prescriptions or over-the-counter medications taken by the user for a given medical condition; the health habits of the user; and the clinical study experience of the user. In FIG. 6K, the user can see if the user has answered completely questions about each medical condition previously listed by the user. In FIG. 6L, the user can provide feedback. In FIG. 6M, the service provider may provide a thank you to indicate that the message was sent successfully.	software that supports account sign-up, management, demographics capture, and personalization of target audiences." (See, page 9). Although the provisional application contemplates (1) providing different levels of access to the general public, pharmaceutical industry users, and sponsors and (2) supporting account sign-up, it does not explicitly disclose a user id and password based registration process for potential subjects of clinical trials. As suggested by Michelson, registration means other than a user id and password login may have been intended (for example, access by e-mail address only).	
"Michelson et al. teaches that an investigator who is [interested] in conducting a clinical study may register on the professional site (see:	Figures 1B, 7A-7C [0099] An investigator who is interested in conducting clinical studies may express his or her interest by registering on the professional site of FIG. 1B. FIGS. 7A, 7B	There is no explicit disclosure in the provisional application of a process by which investigators interested in conducting clinical studies may	209, 244

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paragraph 99 and Figs 1B, 7A-7C)."	and 7C depict investigator questionnaire web page 700 that provides a questionnaire that may be completed by an investigator interested in conducting a clinical study, in accordance with an embodiment of the present invention. In name area 701, the investigator is required to input his or her name. In degree area 702, the investigator's degree(s) are required. The PRF organization or institutional name, address, city state, country, zip code and telephone number are required (and fax and electronic mail address optionally requested) in contact area 703. Specialty area 704 requires that the investigator provide his or her primary specialty area. Board area 705 requires that the investigator indicate whether he or she is board certified and/or board eligible; optionally, the investigator's year of primary specialty board certification, and board information regarding any of the investigator's subspecialties may be provided. In study experience area 706, the investigator is required to indicate the number of years the investigator has participated in clinical studies as well as all phases of clinical research in which the investigator has participated. The	register on a professional study site. There are no FIGs. 1B, 7A-7C or any similar figures disclosed. The provisional application states, "the system includes a clinical trial investigator database 305. The investigator database includes information about the doctors who perform clinical trials, such as name, address, DEA#, trial study experiences, number of studies conducted, when studies were conducted, medical school history, etc. In addition to the raw data, this database includes a proprietary investigator rating scheme. This multidimensional rating scheme includes analyses illustrating the relative performance of the clinical trial investigator over a large number of studies … The investigator database, thus, includes customized database subsets that reflect the	

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	investigator must include the number of investigators that conduct research at the PRF indicated in investigator area 707.	performance of specific sponsor clinical studies. Each contributing sponsor has access to the results and details of its own information." (See, pages 6-7). Although the provisional application discloses a clinical trial investigator database, it does not explicitly disclose means for investigators to directly register on the system. As indicated above, the provisional application does suggest that investigator data, including investigator ratings, is provided to the system by sponsors.	
"Michelson et al. teaches that a subject uses the secure web page to answer all questions in the questionnaire and the answers are stored in the subject database with consent from the patient (see: paragraph 113 and Figs. 15A-15F)."	Figures 15A-15F [0113] After a potential subject has been identified (step 817 or 819), the process of prescreening for participation in the study begins (step 824). In this step, subjects identified using on-line and/or off-line recruitment are notified, and asked whether or not they have an interest in participating in the clinical study. In the case of candidates that were identified on-line	There are no Figures 15A-15F or similar figures in the Provisional. There is no mention in the Provisional of prescreening potential subjects through the use of questionnaires or storing answers to such questionnaires with or without the consent of the potential subjects.	204, 210, 239, 245

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	using the subject database, the subjects are preferably contacted by the means that they identified during their registration on the subject site (e.g., by electronic mail) in order to preliminarily determine whether they have an interest in participating in the clinical study. A screen shot of an exemplary e-mail used for providing such a notification to a potential subject is shown in FIG. 14. The notification could alternatively be provided using telephone, mail, fax or any off-line communication means. If a potential subject responds to a notification by indicating interest in participating in a clinical study, the subject is provided with a formal questionnaire that asks for information specifically relevant to the clinical study. An exemplary study-specific subject questionnaire is shown in reference to FIGS. 15A-15F. In the preferred embodiment, if in response to the e-mail notification shown in FIG. 14, the subject indicates interest in participating in the clinical study, a study-specific subject questionnaire such as shown in FIGS. 15A-15F is provided to the subject on a secure web page found on the subject site. The subject then uses this secure web page to	There are no FIGs. 14 and 15A-15F or any similar figures disclosed. The provisional application states, "The system also includes a patient database 310. The patient database is constructed as to protect the patients' privacy, and includes information about individual patients, such as relevant clinical data, zip code of residence, and e-mail addresses. This database is created through solicitations in advertisements on other Internet sites, through collection of billing and other data from the physician practice management systems of the physician investigators who have private practices, and through managed care organizations, employers, hospital systems, prescription benefit manager, disease management companies, disease advocacy groups, and	

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	answer all of the questions in the subject questionnaire, and to submit such answers for consideration. As mentioned above, irrespective of whether the subject is ultimately selected for participation in the clinical study, these questionnaire answers are stored in the subject database with the consent of the patient, thereby enriching the subject information stored in that database.	physician practice management companies. Further information may be collected from pathology labs to provide more detail about the disease status of oncology patients." (See, page 7). The provisional application states, "tier 3 permits the sponsor access to the identities of the investigators, to the historic investigator trial performance information, and to means with which to communicate with both investigators and patients. Communication with patients protects the patients' privacy. Communications between users of the web site and through e-mails are secure through authentication, encryption, remote access and digital certificates." (See pages 8-9). The provisional application does not explicitly disclose a system whereby potential	

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		subjects answer questionnaires and/or otherwise provide answer to questions transmitted by investigators or sponsors such that the answers are stored in a subject database with consent from the patient.	
"after the pre-screening process, a list of pre-screened subjects who may be eligible to participate in a clinical study is given to the investigator and at step 826, the investigator schedule an appointment with each of the subjects on his or her pre-screened list (see: paragraph 114)."	[0114] Following the pre-screening process described above, a list of pre-screened subjects who may be eligible to participate in a clinical study is given to the investigator. Next, in step 826, the investigator schedules an appointment with each of the subjects on his or her pre-screened list. The subject gets examined and signs an informed consent before the investigator can enroll the subject in a study. In step 830, allocation numbers for each of the subjects selected by the investigator for the clinical study are provided to the sponsor. Since the sponsor must be blind to the identities of the subjects participating in the study, the sponsor is provided with only allocation numbers of the subjects, and no identifying information (such as the name or address of such individuals) is provided to the sponsor.	There is no explicit disclosure in the provisional application of an investigator being provided with a list of pre-screened subjects for scheduling an appointment with each of the subjects from the pre-screened list. The provisional application states, "The inventive system software enables clinical trial investigators and sponsors to identify individuals in the patient database who have a likelihood of qualifying for a particular clinical trial and/or are proximate to an investigator's site." (See, page 9). The provisional application	215, 226

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		further states, "tier 3 permits the sponsor access to the identities of the investigators, to the historic investigator trial performance information, and to means with which to communicate with both investigators and patients. Communication with patients protects the patients' privacy. Communications between users of the web site and through e-mails are secure through authentication, encryption, remote access and digital certificates." (See pages 8-9). Although the provisional application discloses means that enable an investigator to search and identify individuals from the patient database and means for electronically communicating with the individual, the provisional application does not disclose providing the investigator with a prescreened list or the scheduling of an appointment	

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		with each of the prescreened subjects.	
"Michelson et al. teaches at step 2040 [FIG. 20], that after a user has register by completing the registration form, the system asks the person or caregiver to provide simple consent to add the person's information to the database and to give permission to receive notices about clinical studies (see: paragraph 165)"	[0165] Once the person or caregiver is registered, the inventive system evaluates the information provided in the registration form and determines if the person or caregiver should receive notice of a clinical study, as shown in step 2040. For example, the inventive system asks the person or caregiver to confirm that he or she is legally qualified to provide simple consent to add the person's information to the database and to give permission to receive notices about clinical studies. This determination may be based upon information of the person's age, or whether the person or caregiver actually gave permission to receive such notices, for example.	There is no explicit disclosure in the provisional application with regard to providing consent for adding a user's information to the database permission to send notices about clinical studies to the user. In particular, there is no disclosure at all in the provisional application relating to issues of consent. There is no FIG. 20 or any similar figure disclosed. The provisional application states, "The system also includes a patient database 310. ... This database is created through solicitations in advertisements on other Internet sites, through collection of billing and other data from the physician practice management systems of the physician investigators who have private practices, and through managed	205, 214, 216, 217, 227, 228, 230, 239, 240, 245

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		care organizations, employers, hospital systems, prescription benefit manager, disease management companies, disease advocacy groups, and physician practice management companies. Further information may be collected from pathology labs to provide more detail about the disease status of oncology patients." (See, page 7). The provisional application in addition states, "[the] software includes proprietary database matching that enables a comparison of the participant profile to the trials protocol criteria. For example, templates are established for certain protocols and performing database matching to compare this information against the participant entered data." (See, page 9). Although the provisional application allows for the	

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		inclusion of user data in the patient database, it provides no explicit disclosure of means for receiving simple and qualified consent from the user to add the user's information to the database and for receiving permission from the user to send notices about future clinical studies.	
"step 2050 [FIG. 20], where if data regarding a person matches data related to clinical study, the system provides notification to the person or caregiver (see: paragraph 167)."	[0167] If the system determines that the person does not match the geographic location and disease condition of any currently available clinical studies, the inquiry about the person ends. In some embodiments, the system asks the person if the system may contact the person about future studies that may match the criteria set forth in the registration by the person. If, so, when a new study is entered, the person may show up as a potentially eligible subject, and an e-mail or other notification will be delivered to the person. If, on the other hand, the data regarding the person matches data related to a clinical study, the system provides the person or caregiver with notification of the clinical study, as shown as step 2050. This notification may be by e-mail, telephone or	There is no explicit disclosure by the provisional application of a system that sends notifications to users who have consented to receiving such notification when the system determines that user data matches data for a clinical study. There is no FIG. 20 or any similar figure disclosed. The provisional application states, "tier 3 permits the sponsor access to the identities of the investigators, to the historic investigator trial performance information, and	215, 226

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	regular mail, as desired by the person, for example with reference to FIG. 3.	to means with which to communicate with both investigators and patients. Communication with patients protects the patients' privacy. Communications between users of the web site and through e-mails are secure through authentication, encryption, remote access and digital certificates." (See pages 8-9). The provisional application does not disclose a system that sends notification to subjects that have consented to receiving such notification upon the system determining that user data matches data for a clinical study.	